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Attorney Docket No. 10057-704.301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/813,354	Confirmation No.:	5007
Applicant	:	John M. ADAMS et al.		
Filing Date	:	March 29, 2004		
Title	:	Focused Compression Mitral Valve Device and Method		
Group Art Unit	:	3762		
Examiner	:	Scott M. GETZOW		
Docket No.	:	10057-704.301		
Customer No.	:	66854		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313
Sir:

APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 41.37

Appellants submit this brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Final Rejection mailed October 31, 2008. Appellants' Notice of Appeal was filed December 31, 2008. This Appeal Brief is due February 28, 2009 (Saturday) or March 2, 2009 (Monday), and is therefore timely filed.

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I. REAL PARTY IN INTEREST

The real party in interest herein is Cardiac Dimensions, Inc. (Assignee) by virtue of an assignment executed by the inventors (Appellants) to Cardiac Dimensions, Inc. The assignment was recorded by the Assignment Branch of the U.S. Patent and Trademark Office on July 12, 2007 at Reel / Frame 019547 / 0843.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

In the current application under appeal, claims 1-65 are cancelled. Claims 66-76 are pending, and the rejection of these claims is appealed herein.

IV. STATUS OF AMENDMENTS

Appellants have submitted no amendments after the final rejection. All amendments prior to the close of prosecution on the merits have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 66 recites a device that effects the condition of a mitral valve annulus of a heart. The device includes an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus, the elongated member having a relatively low resistance to flexure in a first direction and a relatively high resistance to flexure in a second direction, wherein the first and second directions lie in the same plane.

Support for this claim can be found in at least the embodiments shown in Figures 6 and 7, and paragraphs [0059]-[0064].

Independent claim 71 recites a device that effects the condition of a mitral valve annulus of a heart. The device includes an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus, the elongated member having a relatively low resistance to flexure in a first direction and a relatively high resistance to flexure in a second direction, wherein the elongated member includes a first longitudinal side facing the first

direction and a first plurality of notches formed in the first longitudinal side to provide the elongated member with the relatively low resistance to flexure in the first direction, and wherein the elongated member includes a second longitudinal side facing the second direction and a second plurality of notches formed in the second longitudinal side to render the elongated member stable when flexed in the second direction.

Support for this claim can be found in at least the embodiments shown in Figures 6 and 7, and paragraphs [0059]-[0064].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants respectfully request the Board of Patent Appeals and Interferences to review the following grounds of rejection on appeal:

1. Whether claims 66-76 are patentable under 35 U.S.C. § 103(a) over Colvin et al., U.S Pat. No. 6,602,289 ("Colvin").

VII. ARGUMENTS

Appellants respectfully submit that claims 66-76 are in proper form and are patentable over the prior art of record.

The Examiner bears the initial burden of establishing a *prima facie* case of nonpatentability. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). A *prima facie* case of obviousness requires a determination of (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. *KSR International v. Teleflex, Inc.*, 550 U.S. 398, 127. S.Ct. 1727, 167 L.Ed. 705, 710, 82 USPQ2d 1385 (2007), *quoting Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The obviousness or nonobviousness of the subject matter is determined against this background. *Id.*

1. Rejection of Claims 66-76 over Colvin

The Examiner rejected claims 66-76 under § 103(a) as being unpatentable over Colvin. This rejection is improper and should be overturned for at least the reasons set forth below.

Colvin

Colvin discloses and teaches an "annuloplasty device" (Col. 4, lines 55-56) which is to be implanted and secured to a native valve annulus (Col. 4, line 63 – Col. 5, line 1). The annuloplasty device "provides annular remodeling similar to that achieved when using a complete annuloplasty ring." (Col. 4, lines 61-63).

Claim 66

Independent claim 66 requires a device comprising "an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus." Applicants' Figure 1 shows exemplary relative positions of coronary sinus 18 and mitral valve annulus 20 (see paragraphs [0045] and [0046]). Applicants illustrate exemplary devices which are dimensioned to be placed in the coronary sinus in Figures 2-12.

The devices in Colvin are designed to be implanted within a different region of the heart than the devices in Applicants' specification. The devices in Colvin are designed to be secured to an annulus in the heart, while Applicants' device is designed to delivered to and deployed in the coronary sinus. Applicants describe differences in these approaches and devices in paragraphs [0006]-[0009].

Colvin describes an annuloplasty ring which is specifically "shaped and sized for attachment to the inner surface of a heart valve annulus. More precisely, the present invention is **shaped** to compliment the valve annulus since it [is] matches the general ovoid shape of the native heart annulus." (Col. 5, line 65 – Col. 6, line 1 (emphasis added); also see Abstract lines 1-2). Colvin also states that "[w]hen implanted, the annuloplasty device is shaped similar to a broad 'U'." (Col. 5, lines 15-16). Additionally, Colvin states that the "shape" of the device is "necessary for simultaneously achieving good annular remodeling, physiologic movement of the valve annulus, and ease of implantation." (Col. 3, lines 6-10).

The device as described and shown in Colvin is dimensioned for attachment to the inner surface of a heart valve annulus, and is not dimensioned to be placed in the coronary sinus of the heart, as is required by independent claim 66 (also compare Applicants' Figure 1 and Colvin's Figure 5). The coronary sinus and the mitral valve annulus have anatomically different shapes and the annuloplasty device described in Colvin ("shaped to … match the general ovoid shape of the native heart annulus") is not dimensioned to be placed in the coronary sinus as is required by

claim 66. Additionally, the device in Colvin is implanted in a surgical procedure, and "[a]t the time of surgical implantation, the surgeon, with the aid of a template sizer, will choose the appropriately sized annuloplasty device, and fit the device to the valve annulus." (Col. 5, lines 36-39). The size and generally ovoid shape of the Colvin device allow it to be surgically secured to the valve annulus, but not surgically implanted in the coronary sinus.

Independent claim 66 also requires that "the elongated member having a relatively low resistance to flexure in a first direction and a relatively high resistance to flexure in a second direction, wherein the first and second directions lie in the same plane." While Colvin does state that "support member 16 may also be designed to bend preferentially or exclusively in one or more directions," (Col. 6, lines 12-14), it does not teach, suggest, or appreciate having relatively low and high resistances to flexure in a first and second directions, wherein the first and second directions lie in the same plane. Colvin does not describe how the device may bend once implanted in the heart, and therefore does not appreciate providing a device wherein the first and second directions lie in the same plane.

Colvin does not teach or suggest all of the limitations of independent claim 66. It would not have been obvious to modify the teachings of Colvin to arrive at claim 1 because Colvin teaches a fundamentally different device which is adapted to be implanted in a different location of the heart.

Claims 67-68 and 71-75

Dependent claim 67 depends from claim 66 and requires that the elongated member include a first longitudinal side facing the first direction and a first plurality of notches formed in the first longitudinal side to provide the elongated member with the relatively low resistance to flexure in the first direction. The Examiner states that it would have been obvious to put notches on the device in that such reduction in structural integrity is known to make one side more flexible than another (pg. 3, 3/18/2008 Office Action). Applicants contend it would not have been obvious to include notches on the device in Colvin. As described above, the device in Colvin is attached directly to an annulus of the heart. While Colvin acknowledges that the flexibility of the device preferably allows the device "to be bent slightly during the cardiac cycle" (Col. 5, lines 25-27), it is possible that adding notches would increase the device's susceptibility to fatigue or even fracture, as the forces exerted on Colvin's device (which is implanted within a chamber of the heart) during contraction of the heart may be greater than

forces exerted on a device implanted in the coronary sinus. As Colvin's device and Applicants' device are adapted to be implanted in different locations in the heart, it is not obvious that a feature which is included in one device can be incorporated into the other device.

Claims 69, 70 and 76

Claims 69 and 76 (and claim 70 which depends from claim 69) recite that the elongated member is bent to conform to the shape of the coronary sinus when in a first orientation. As discussed above, the Colvin device is shaped to have a generally ovoid shape. A device with a generally ovoid shape as described in Colvin does not conform to the shape of the coronary sinus. While Colvin does state that device can be "bent slightly" (Col. 5, line 26), Colvin does not teach, suggest, or appreciate a device that can be bent to conform to the shape of the coronary sinus when in a first orientation, as required in claims 69, 70 and 76.

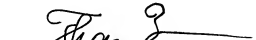
Colvin does not teach or suggest all of the limitations of these rejected claims. It would not have been obvious to modify the teachings of Colvin to arrive at a device with an elongated member that is bent to conform to the shape of the coronary sinus when in a first orientation because the device in Colvin is secured to a valve annulus.

CONCLUSION

For the reasons stated above, claims 66-76 are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. § 103(a) are improper and should be withdrawn. Appellants respectfully ask the Board to overturn the Examiner's rejection with instructions to allow the claims.

Respectfully submitted,

Date: March 2, 2009

By: 

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VIII. CLAIMS APPENDIX

1. – 65. (Canceled).

66. (Previously Presented) A device that effects the condition of a mitral valve annulus of a heart comprising an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus, the elongated member having a relatively low resistance to flexure in a first direction and a relatively high resistance to flexure in a second direction, wherein the first and second directions lie in the same plane.

67. (Previously Presented) The device of claim 66 wherein the elongated member includes a first longitudinal side facing the first direction and a first plurality of notches formed in the first longitudinal side to provide the elongated member with the relatively low resistance to flexure in the first direction.

68. (Previously Presented) The device of claim 67 wherein the elongated member includes a second longitudinal side facing the second direction and a second plurality of notches formed in the second longitudinal side to render the elongated member stable when flexed in the second direction.

69. (Previously Presented) The device of claim 66 wherein the elongated member is bent to conform to the shape of the coronary sinus when in a first orientation.

70. (Previously Presented) The device of claim 69 wherein the elongated member has a first radius of curvature when in the first orientation, a second radius of curvature when in a second orientation, and wherein the first radius of curvature is less than the second radius of curvature.

71. (Previously Presented) A device that effects the condition of a mitral valve annulus of a heart comprising an elongated member dimensioned to be placed in the coronary sinus of the heart adjacent the mitral valve annulus, the elongated member having a relatively low resistance to flexure in a first direction and a relatively high resistance to flexure in a second direction, wherein the elongated member includes a first longitudinal side facing the first direction and a

first plurality of notches formed in the first longitudinal side to provide the elongated member with the relatively low resistance to flexure in the first direction, and wherein the elongated member includes a second longitudinal side facing the second direction and a second plurality of notches formed in the second longitudinal side to render the elongated member stable when flexed in the second direction.

72. (Previously Presented) The device of claim 71 wherein the first plurality of notches are larger than the second plurality of notches.

73. (Previously Presented) The device of claim 72 wherein the first and second directions lie in the same plane.

74. (Previously Presented) The device of claim 71 wherein the first and second longitudinal sides are opposite each other.

75. (Previously Presented) The device of claim 74 wherein the first and second directions lie in the same plane.

76. (Previously Presented) The device of claim 71 wherein the elongated member is bent to conform to the shape of the coronary sinus when in a first orientation.

IX. EVIDENCE APPENDIX

1. Colvin et al. US 6,602,289 cited by the Examiner in the non-final Office Action mailed 3/18/2008.

X. RELATED PROCEEDINGS APPENDIX

None.